EUROPEAN COMMISSION

Bruxelles, 15.3.2013
C(2013)1711 (final)

COMMISSION IMPLEMENTING DECISION

of 15.3.2013

concerning the transfer of the designation of "Gemtuzumab Ozogamicin" as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1], and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted on 20 February 2013 by Wyeth Europa Limited under Article 5(11) of Regulation (EC) No 141/2000,

Having regard to the opinion of the European Medicines Agency,

Whereas:

(1) By Decision C(2000)3025 of 18 October 2000 the medicinal product "Gemtuzumab Ozogamicin" was designated as an orphan medicinal product and entered in the Community Register of Orphan Medicinal Products pursuant to Article 5(9) of Regulation (EC) No 141/2000.

(2) A change of designation holder is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already designated as an orphan medicinal product.

(3) The application should therefore be granted,

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[1] OJ L 18, 22.1.2000, p.1.

HAS ADOPTED THIS DECISION:

Article 1

The designation of the medicinal product "Gemtuzumab Ozogamicin" as an orphan medicinal product, entered in the Community Register of Orphan Medicinal Products under number EU/3/00/005 and held by Wyeth Europa Limited, is transferred to Pfizer Limited.

Article 2

This Decision is addressed to:
1. Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom
and
2. Wyeth Europa Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom.

Done at Brussels, 15.3.2013.

For the Commission
Paola TESTORI COGGI
Director-General